K092486
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3.0 510(k) Summary

Date: April 16, 2009

AUG 28 2009

Sponsor of the 510(k): Vortex Medical
50 Loring Drive
Norwell, MA 02061

Contact: Brian Kunst, Regulatory Affairs Consultant
518-796-6346

Device Identification:

Trade Name	**Vortex Medical AngioVac Cardiopulmonary Bypass Circuit**
Common Name	Cardiopulmonary Bypass Tubing and Accessories
Classification Names	Tubing, Pump, Cardiopulmonary Bypass 21 CFR §870.4390, Cardiovascular, 74 DWE (Class II)
	Adaptor, Stopcock, Manifold, or Fitting, Cardiopulmonary Bypass 21 CFR §870.4290, Cardiovascular, 74 DTL (Class II)

Legally marketed devices to which equivalence is claimed:

Terumo Pump Tubing K013578
Gish Biomedical Tubing Connectors K833322, K030077
Terumo Circuit Connectors K041697
Cobe Cardiovascular Tubing Sets K881330, K771692
Maquet Cardiopulmonary Jostra HLM Tubing Set K053025

Intended Use / Indications

Intended for use in procedures requiring extracorporeal circulatory support for periods of up to six hours. This is the same intended use as other commercially available cardiopulmonary bypass procedure kits and accessories.

Device Description

The Vortex Medical AngioVac Cardiopulmonary Bypass Circuit and Accessories consists of:

Component	
Tuohy Borst Adapter	Y Connectors
Non-Vented Spike	Colder MPX Series Coupling Body (In-Line Hose Barb with Lock - Male)
Vented Cap	Colder MPX Series Coupling Insert (In-Line Hose Barb - Female)
PVC tubing .375"ID	Reducers
PVC tubing .500" ID	Adhesive backed tubing holder
PVC tubing .250" ID	Pinch Clamps ("Roberts")

Substantial Equivalence

The subject and predicate devices are substantially similar in configuration, dimensions, and materials. The types of components in the kit are well known and have a long history of safe and effective medical application.

Summary of the non-clinical performance data

Connection strength and system integrity testing was performed to verify the integrity of the fittings and the assembled system.

Summary of the clinical performance data

No clinical tests were performed to determine substantial equivalence.

Conclusions drawn from the non-clinical performance data

The non-clinical tests demonstrate that the device is equivalent to the performance of currently available cardiopulmonary bypass tubing sets and accessories and is considered as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 2 8 2009

Vortex Medical, Inc.
c/o Mr. Morten Christensen
Underwriters Laboratories, Inc.
455 E. Trimble Road
San Jose, CA 98131

Re: K092486
Trade/Device Name: Vortex Medical AngioVac Cardiopulmonary Bypass Circuit
Regulation Number: 21 CFR 870.4390
Regulation Name: Cardiopulmonary bypass pump tubing
Regulatory Class: Class II
Product Code: DWE
Dated: August 7, 2009
Received: August 13, 2009

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092486

2.0 Indications for Use Statements

Indications for Use

510(k) Number (if known):

Device Name: Vortex Medical AngioVac Cardiopulmonary Bypass Circuit

Indications for Use:

Indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

Prescription Use ___X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K092486